ORAL TISSUE CONTOURER

Related Applications

[0001] This application claims priority from U.S. Provisional Patent Application Number 60/455,629, which was filed on March 18, 2003, and is entitled "Tissue Expander and Method of Using". This application is related to the co-pending application, "Method of Using a Tissue Contourer", filed contemporaneously herewith, which is incorporated by reference herein for all that it teaches.

Field of the invention

[0002] This invention relates to oral surgery. More particularly, it relates to the anatomical contouring of tissue for augmentation of the residual alveolar bone structures with grafting procedures. Even more particularly, it relates to contouring the oral mucosal tissue back to normal anatomical contours by inserting an inflatable bladder submucosally or subperiosteally prior to surgical grafting procedures.

Background of the Invention

[0003] The normal topography of the gingival tissue around teeth has interpapillary and root prominence contours which are determined by the alveolar processes present in normal bone.

[0004] When a patient loses a tooth or teeth, he also loses the tissue and bone contours that support the tooth or teeth and that give it a natural appearance. This loss results in a recontouring of the tissue and bone to the contours of an atrophic residual edentulous ridge area which is generally round in shape and lacks natural bone and tissue contours.

[0005] As the bone continues to be resorbed over time, it continues to change in a direction that is not a straight vertical or horizontal direction but in a much-defined diagonal direction. The maxillary arch will resorb in an upward and

lingual direction and the mandibular arch will resorb in a downward and facial direction. The maxillary arch decreases in vertical height and becomes narrower. The mandibular arch also decreases in vertical height but becomes broader. In order to restore normal contours to the tissue and bone, we must first recontour the tissue to normal contours and then graft the residual bone back to its normal contours. In this way, we can regenerate the natural appearance of the tissue and the bone. It is not just a matter of increasing vertical dimension but a complex dimensional change. For grafting procedures to be surgically successful, they need to be covered with vascularized mucosal tissue to aid in bone growth and to prevent infection. It is also necessary to have a tension free primary closure of the incision. If the incorrect contour of the tissue is used, incomplete coverage of the bone graft will occur or a tension in the tissue will occur resulting in a dehiscence of the tissue and exposure of the graft. When these outcomes are present, the patient will loose some of the bone graft material and will allow the site to become infected.

[0006] Devices for creating tubular channels in mucosal tissue have been proposed in the past, but have failed for their intended purposes. For example, U.S. Patents 4,798,205 and 4,719,918 suggest devices for enhancing the retention for complete dentures.

[0007] In the arrangement of the '918 and '205 patents, a void or channel is created in the mucosal tissues along the crest of a totally edentulous ridge. This void or channel extends completely around the maxillary and mandibular arches. A granular form of hydroxyl appetite material is inserted into a channel along the crest of an eroded maxillary or mandibular ridge to increase the volume of the ridge and hence provide better engagement with and retention of a complete denture.

[0008] At the time of the '918 and '205 patents, industry expectations were that a semi-rigid HA material, if properly placed between the bone and tissue

would support a complete denture and enhance retention. The material would remain in place and help distribute the load evenly.

[0009] In the '205 patent, a midline incision is made in the mandible or the maxilla at the mid-crestal line. Two channels are made that extend from the midline along the crest of the bone in both directions, each terminating at an exist incision at the tuberosity on the maxilla and at the retromolar pad of the mandible.

[0010] Once the two channels are made, a thread is inserted into each channel through the mid-crestal incision to the posterior incisions. These threads are connected to two opposing ends of an elongated bladder.

[0011] Once they have been inserted through the midline incisions, the ends of the threads are drawn through the posterior incisions until they have been completely removed and the bladder is completely inserted into the channels.

[0012] Once in this position, the bladder is inflated. The inflated bladder creates the channel in which the HA is subsequently inserted.

[0013] Unfortunately, the channel created by this process doesn't prevent the migration of the granules into the mucosal tissues, which in return permits the loss of retention for the complete denture and the tissue dehiscence by the HA granules. This process was ultimately unsuccessful and has been abandoned by the dental practitioners.

[0014] What is needed is a tissue contourer for creating vascularized mucosal tissue with normal tissue contours that can be used for surgical grafting procedures. What is needed is a device that is configured to create this tissue in an edentulous space between existing teeth. What is also needed is a tissue contourer having a volume of between 0.5 milliliters and 31.2 milliliters to create a short recontoured tissue pocket having a similar volume. What is also needed is a tissue contourer having a length of between 6.9 millimeters and 71.2 millimeters and configured to be disposed in an edentulous gap of similar length with contourer ends adjacent to and preferably abutting the terminal teeth. What is

also needed is a device for creating a recontoured tissue pocket that is configured to be placed in an edentulous gap of one to eight teeth.

[0015] It is an object of this invention to provide a device having these capabilities in one or claimed embodiments thereof.

Summary of the Invention

[0016] In accordance with a first embodiment of the invention, a tissue contourer or expander is provided having an expandable or an inflatable bladder. This bladder may be inserted under mucosal tissue overlying eroded bone and gradually inflated. By gradually inflating the contourer, the overlying mucosal tissue is encouraged to stretch, expand or otherwise increase its surface area to accommodate the inflated bladder and thereby produce a desired surface contour of the mucosal tissue. This encourages growth and an increase in vascularity of the expanded tissue.

[0017] As the mucosal tissue grows, its internal tension is relieved. The bladder can be further and successively inflated or expanded as the tissue expands to provide a void, space or chamber between the bone and the mucosal tissue into which (once the tissue contourer is removed) a bone graft, bone growth enhancer, implant or other prosthetic device that supports the contoured tissue to resemble the bone contours that would have existed were it not for tooth loss and bone erosion.

[0018] In accordance with a second embodiment of the invention, a tissue contourer for contouring mucosal tissue in preparation for dental implantation or grafting is provided, the contourer including a central portion having a first side configured to abut an edentulous portion of a maxilla or mandible and a second side configured to contour mucosal tissue overlying the edentulous portion; a first end extending from the central portion and configured to abut a first tooth at one end of the edentulous gap; a second end extending from the central portion and

configured to abut another tooth at another end of the edentulous gap; and a means for filling the central portion with fluid.

[0019] The first end, the second end and the central portion may have an overall length of no more than 71.2 mm, 52 mm, or 26 mm. The contourer may have an internal working volume of no more than 31.2 ml, 22.1 ml, or 5 ml.

[0020] In accordance with a third embodiment of the invention, a tissue contourer bladder for contouring mucosal tissue in preparation for dental implantation or grafting is provided, the bladder including an elongate central portion configured to be disposed between a maxilla or mandible and mucosal tissue overlying the maxilla or mandible; a first end configured to be disposed in a first terminal gap; and a second end configured to be disposed in a second terminal gap.

[0021] The first and second terminal gaps may be the same terminal gap. The first and second terminal gaps may be in the same quadrant. The first and second terminal gaps may be in adjacent quadrants.

[0022] In accordance with a fourth embodiment of the invention, a tissue contourer for contouring mucosal tissue in preparation for dental implantation or grafting is provided, the contourer including a bladder having an elongated central portion with a texture, wherein the central portion is configured to be disposed between a maxilla or mandible and overlying mucosal tissue; a first end configured to be disposed in a first terminal gap; and a second end configured to be disposed in a second terminal gap.

[0023] The texture may be defined by a plurality of protrusions extending outward away from a surface of the central portion. The texture may be further defined by a plurality of concavities extending inwardly from the surface of the central portion. The texture may be defined by a plurality of concavities extending inwardly from a surface of the central portion. The texture may be defined by a plurality of elongated concavities or protrusions. The elongated concavities or

protrusions may be formed as elongated ovals. The elongated ovals may be disposed at an angle to its adjacent elongated ovals.

[0024] In accordance wit ha fifth embodiment of the invention, a tissue contourer for contouring mucosal tissue in preparation for dental implantation or grafting is provided, the contourer including an elongated central portion having a top side, a bottom side, a facial-facing side, and a lingual-facing side, wherein at least one of the four sides is stiffer than the other three sides; a first end configured to be disposed in a first terminal gap at one end of an edentulous gap; and a second end configured to be disposed in a second terminal gap at another end of the edentulous gap.

[0025] The bottom side may be stiffer than the top side. The facial-facing and lingual-facing sides may be stiffer than the top side. The elongated central portion may be a polygon in at least one cross-section. The elongated central portion may be a quadrilateral in at least one cross-section. The elongated central portion may be a regular polygon in at least one cross-section. The two ends may be stiffer than the top side.

[0026] In accordance with a sixth embodiment of the invention, a tissue contourer for contouring mucosal tissue in preparation for dental implantation or grafting is provided, the contourer including a cylindrical elongated central portion with at least one longitudinal cross-section that is a conic section; a first end configured to be disposed in a first terminal gap at one end of an edentulous gap; and a second end configured to be disposed in a second terminal gap at another end of the edentulous gap.

[0027] The conic section may be a circle. The conic section may not change when the tissue contourer is filled with fluid. The elongated central portion may be made of a self-sealing material.

[0028] In accordance with a seventh embodiment of the invention, A tissue contourer for contouring mucosal tissue in an edentulous gap in preparation for

dental implantation or grafting, the contourer including a central portion configured to contour mucosal tissue overlying the edentulous gap; a first end configured to be disposed in a first terminal gap at one end of the edentulous gap; a second end configured to be disposed in a second terminal gap at another end of the edentulous gap; and a means for filling the central portion with fluid.

[0029] The means for filling the central portion with fluid may include a membrane means for limiting fluid leakage from the contourer. The means for filling the central portion with fluid may include an annulus defining an opening through which fluid is introduced into the central portion. The means for filling the central portion may include a means coupled to and between the annulus and the central portion to direct fluid from the annulus to the central portion.

[0030] In accordance with an eighth embodiment of the invention, a tissue contourer for contouring mucosal tissue in an edentulous gap in preparation for dental implantation or grafting is provided, the contourer including a central portion configured to contour mucosal tissue overlying the edentulous gap; a first end coupled to the central portion and configured to be disposed in a first terminal gap at one end of the edentulous gap; and a second end coupled to the central portion configured to be disposed in a second terminal gap at another end of the edentulous gap.

[0031] The central portion may have a top surface and the central portion may include a plurality of projections disposed on the top surface and extending upwardly therefrom. The plurality of projections may be spaced between 2 and 10 mm apart. The plurality of projections may be disposed to contour papillae in the mucosal tissue. The plurality of projections extend between 1 and 5 mm upward from the top surface.

[0032] In accordance with a ninth embodiment of the invention, a tissue contourer for contouring mucosal tissue in an edentulous gap in preparation for dental implantation or grafting is provided, the contourer including a bladder having a central portion configured to contour mucosal tissue overlying the

edentulous gap, a first end configured to be disposed in a first terminal gap at one end of the edentulous gap, and a second end configured to be disposed in a second terminal gap at another end of the edentulous gap, and the bladder defines at least one passageway extending therethrough.

[0033] The passageway may extend from a top surface through a bottom surface of the bladder.

[0034] The means for filling the second embodiment may be selected from the group consisting of a self-sealing portion of central portion and a port

[0035] These and other objects, advantages and aspects of the invention will become apparent from the following description. In the description, reference is made to the accompanying drawings, which form a part hereof, and in which there is shown a preferred embodiment of the invention. Such embodiment does not necessarily represent the full scope of the invention and reference is made therefore, to the claims herein for interpreting the scope of the invention.

<u>Brief Description of the Drawings</u>

[0036] **FIGURE 1** shows a first embodiment of a tissue contourer.

[0037] **FIGURE 2** shows another embodiment of the tissue contourer of **FIGURE 1** having a port connected to a bladder.

[0038] **FIGURE 3** shows a side view of the tissue contourer of **FIGURE 2**.

[0039] **FIGURE 4** is a cross-sectional view of the tissue contourer of **FIGURES 2-3** taken at Section Line 3-3 in **FIGURE 3** and showing how the port provides access to the inside of the bladder.

[0040] **FIGURE 5** shows another embodiment of the tissue contourer of the foregoing **FIGURES** wherein the port includes an elongated tube that is preferably constructed of the same material as the bladder.

[0041] **FIGURE 6** is a cross-sectional view of the tissue contourer of **FIGURE 5**, taken at Section Line 5-5 looking down the end of the tissue contourer where the elongated tube connects to the bladder.

[0042] **FIGURE 7** is an end view of the tissue contourer depicted in **FIGURES 5** and **6** showing the bladder's cylindrical form and closed end.

[0043] **FIGURE 8** is a fragmentary view of another embodiment of the tissue contourer of any of the foregoing **FIGURES**, showing one end of the bladder modified to include a probe-engaging nosepiece.

[0044] **FIGURE 9** is a cross-sectional view of the device of **FIGURE 8** taken at Section Line 8-8, and shows two nosepiece hollows, one that forms the end of the bladder and one that receives an insertion probe.

[0045] **FIGURE 10** is a side view of the device of **FIGURES 8** and **9** showing the insertion probe fitted into a nosepiece hollow.

[0046] **FIGURE 11** is an end view of the device of **FIGURES 8-10** showing the convex side of the nose piece, which faces outward from the bladder.

[0047] **FIGURES 12** and **13** show details of the port arrangement of **FIGURES 5-7**.

[0048] **FIGURE 12** is a fragmentary view of the tissue contourer showing the port and the end of the bladder to which it is attached, with the annular structure shown in perspective.

[0049] **FIGURE 13** is a cross-sectional view of the fragmentary structure shown in **FIGURE 12**, with the cutting plane extending generally parallel to the longitudinal axis of the tube and the bladder.

[0050] **FIGURES 14-16** show an alternative valve arrangement useable with any of the ports of any of the tissue contourers disclosed or described herein.

[0051] **FIGURE 14** is a cross-sectional side view of a port having a self-sealing membrane differing from the arrangement of **FIGURES 12-13** in the membrane and annulus arrangement.

[0052] **FIGURE 15** is a top view of the port of **FIGURE 14**.

[0053] **FIGURE 16** is a cross-sectional view of the port of **FIGURES 14** and **15** taken at Section Line 14-14 in **FIGURE 14**.

[0054] **FIGURE 17** shows a typical prior art hypodermic needle used to fill the ports of **FIGURES 2-7** and **12-16** with fluids such as a sterile saline solution.

[0055] **FIGURES 18** and **19** show an alternative port arrangement with a mechanical check valve that is configured to be used with any of the tissue contourers disclosed herein.

[0056] **FIGURE 20** illustrates a syringe configured to mechanically engage with the ports of **FIGURES 18, 19, 21** and **22** to introduce fluid into any tissue contourer bladder to which the port of **FIGURE 19** is coupled.

[0057] **FIGURES 21** and **22** are top and side cross-sectional views of alternative port arrangements of the port of **FIGURE 18** and **19** in which the planar valve element and spring have been replaced with a spherical valve element.

[0058] **FIGURE 23** is a side view of a rectangular bladder of an alternative tissue contourer.

[0059] **FIGURE 24** is a cross-sectional view of the tissue contourer bladder of **FIGURE 23** showing its square cross-section. The cross-section is taken at Section Line 23-23 in **FIG. 23**.

[0060] **FIGURE 25** is a side view of the tissue contourer of **FIGURES 23** and **24** showing it in its expanded condition.

[0061] **FIGURE 26** is a cross-sectional view of the tissue contourer of **FIGURES 23-25** showing the tissue contourer in its expanded condition. The cross-section is taken at Section Line 25-25 in **FIG. 25**.

[0062] **FIGURE 27** shows another embodiment of the tissue contourer bladder of **FIGURES 23-24** in an alternate expanded form.

[0063] **FIGURE 28** shows a cross-sectional view of the tissue contourer of **FIGURE 27** taken at Section Line 27-27.

[0064] **FIGURE 29** is a perspective view of another embodiment of a tissue contourer bladder having a circular cross-section.

[0065] **FIGURE 30** is a side view of the tissue contourer bladder of **FIGURE 29.**

[0066] **FIGURE 31** is a cross-sectional view of the tissue contourer of **FIGURES 29** and **30** taken at Section Line 30-30 in **FIGURE 30.**

[0067] **FIGURE 32** is a side view of the tissue contourer bladder of **FIGURES 29-31** shown as it would appear when expanded.

[0068] **FIGURE 33** is a cross-sectional view of the tissue contourer bladder of **FIGURES 29-32** taken at Section Line 32-32 in **FIGURE 32.**

[0069] **FIGURES 34A, 34B, 35, 36,** and **37** show another alternative tissue contourer bladder in the form of a generally circular dome with an expandable top.

[0070] **FIGURE 34A** is a side view of the tissue contourer bladder.

[0071] **FIGURE 34B** is a cross-sectional view of the tissue contourer bladder taken at Section Line 34-34 in **FIGURE 34A.**

[0072] **FIGURE 35** is a plan view of the tissue contourer bladder of **FIGS. 34A** and **34B.**

[0073] **FIGURE 36** is a side view of the tissue contourer bladder of **FIGS. 34A** and **34B** showing the bladder both in an unexpanded (indicated by the dashed line) and an expanded (indicated by the solid line) condition.

[0074] **FIGURE 37** is a cross-sectional view of the tissue contourer bladder taken at Section Line 36-36 in **FIGURE 36** and showing the bladder both in an unexpanded (indicated by the dashed line) and an expanded (indicated by the solid line) condition.

[0075] **FIGURES 38, 39, 40**, and **41** show another alternative tissue contourer bladder in the form of a generally circular cylinder having generally hemispherical ends.

[0076] **FIGURE 38** is a top view of the bladder.

[0077] **FIGURE 39** is a cross-sectional view of the bladder taken at Section Line 38-38 in **FIGURE 38**.

[0078] **FIGURE 40** is a top view of the bladder showing it in expanded (the solid line) and unexpanded (the dashed line) condition.

[0079] **FIGURE 41** is a cross-sectional view of the tissue contourer bladder taken at Section Line 40-40 in **FIGURE 40**.

[0080] **FIGURES 42-45** show another alternative tissue contourer bladder in the form of a generally planar and elongate oval. The bladder of **FIGS. 42-45** would appear as an elongated oval in plan view as shown in **FIG. 38**.

[0081] **FIGURE 42** is a side view of the bladder.

[0082] **FIGURE 43** is a cross-sectional view of the bladder taken at Section Line 42-42 in **FIGURE 42**.

[0083] **FIGURE 44** is a side view of the bladder showing it in expanded (the solid line) and unexpanded (the dashed line) condition.

[0084] **FIGURE 45** is a cross-sectional view of the tissue contourer bladder taken at Section Line 44-44 in **FIGURE 44**.

[0085] **FIGURES 46-49** are plan views of any of the tissue contourer bladders illustrated or described herein showing alternative plan configurations of those bladders in a succession of plan views.

[0086] **FIGURES 50** and **51** illustrate another configuration of the tissue contourer bladder of **FIGURES 34A**, **34B**, **35**, **36**, and **37**.

[0087] **FIGURE 50** is a side view of the bladder.

[0088] **FIGURE 51** is a cross-sectional view of the bladder showing thickness differences that permit the upper portion to expand more than the lower portion of the bladder. This view is taken at Section Line 50-50 in **FIG. 50**.

[0089] **FIGURES 52** and **53** show another configuration of the tissue contourer bladder of **FIGURES 27** and **28** having preferred wall thicknesses.

[0090] **FIGURE 52** is a cross-sectional side view of the bladder.

[0091] **FIGURE 53** illustrates the same view as that of **FIGURE 52**, but shows the bladder in an inflated condition.

[0092] **FIGURES 54**, **55**, and **56** illustrate an alternative tissue contourer bladder configuration having walls of differing thickness to control expansion.

[0093] **FIGURE 54** is a perspective view of the bladder illustrating its cylindrical shape with generally flat ends and having a longitudinal axis and a Section Line 54-54 extending coplanar with the longitudinal axis.

[0094] **FIGURE 55** is a cross-sectional view of the bladder of **FIGURE 54** taken along Section Line 54-54.

[0095] **FIGURE 56** is a cross-sectional view of the tissue contourer of **FIGURES 54** and **55** taken along the same Section Line as **FIGURE 55**, but showing the tissue contourer bladder in an expanded condition.

[0096] **FIGURES 57** and **58** are cross-sectional views of another tissue contourer bladder having the outward appearance of the bladder of **FIGURES 38-41**, but having varying wall thicknesses to control bladder expansion upon inflation.

[0097] **FIGURE 57** is a longitudinal cross-section of the bladder in an unexpanded condition.

[0098] **FIGURE 58** is a longitudinal cross-section of the bladder in an expanded condition.

[0099] **FIGURES 59** and **60** are cross-sectional views of another tissue contourer bladder having the outward appearance of the bladder of **FIGURES 38-41**, but having varying wall thicknesses to control expansion upon inflation.

[00100] **FIGURE 59** is a longitudinal cross-section of the bladder in an unexpanded condition.

[00101] **FIGURE 60** is a longitudinal cross-section of the bladder in an expanded condition.

[00102] **FIGURES 61A, B, C, D,** and **E** illustrate different surface textures with which any of the tissue contourer bladders disclosed herein can be provided.

[00103] **FIGURE 61A** is a fragmentary plan view of a bladder with a pattern of circular protrusions or concavities.

[00104] **FIGURE 61B** is a fragmentary plan view of a bladder with a pattern of elongate oval protrusions or concavities disposed both parallel and perpendicular to the length of the tissue contourer bladder.

[00105] **FIGURE 61C** is a fragmentary plan view of a bladder with a pattern of elongate oval protrusions or concavities disposed diagonally across the tissue expander bladder.

[00106] **FIGURE 61D** is a fragmentary plan view of a bladder with a pattern of elongated rectangular protrusions or concavities disposed longitudinally and laterally.

[00107] **FIGURE 61E** is a fragmentary plan view of a bladder with a pattern of elongated rectangular protrusions or concavities disposed diagonally along the bladder.

[00108] **FIGURES 62A**, **B**, and **C** are fragmentary cross-sections through the wall of each of the bladders of **FIGURES 61A**, **B**, **C**, **D**, and **E**, illustrating alternative arrangements of the protrusions and concavities.

[00109] **FIGURE 62A** shows the patterns of **FIGURES 61A**, **B**, **C**, **D**, and **E** in cross-section in which all the protrusions or concavities are concavities extending inward generally toward the center of the bladder.

[00110] **FIGURE 62B** shows the protrusions or concavities extending outward generally away from the center of the bladder.

[00111] **FIGURE 62C** shows the protrusions or concavities extending alternately and generally inward toward and outward away from the center of the bladder.

[00112] **FIGURES 63-65** illustrate an alternative tissue contourer bladder having a generally vertically-extending wall that defines a passageway therethrough.

[00113] **FIGURE 63** is a plan view of the bladder showing the upper end of the passageway.

[00114] **FIGURE 64** is a cross-sectional side view of the bladder taken at Section Line 63-63 in **FIGURE 63** showing the vertically extending walls of the passageway.

[00115] **FIGURE 65** is a side view of the bladder.

[00116] **FIGURES 66-67** illustrate an alternative tissue contourer bladder having a plurality of contouring projections extending upward from its upper surface.

[00117] **FIGURE 68** is a plan view of an alternative tissue contourer bladder constructed according to that of **FIGURES 66-67**, having four generally vertical passageways extending therethrough that are defined between each of four upwardly extending contouring projections.

[00118] **FIGURE 69** is a cross-sectional view of the tissue contourer of **FIGURE 68** taken at Section Line 68-68 in **FIGURE 68**.

[00119] **FIGURES 70 and 71** show a connector for joining two bladders to a single port for joint and simultaneous filling and emptying.

In many of the embodiments illustrated in the **FIGURES** above, the walls of the tissue contourer bladder are shown in cross-section and are shown as having a significant cross-sectional thickness with respect to the overall dimensions of the tissue contourer bladder itself. The actual thickness of the walls can vary widely as recited herein. It is only by showing walls with a significant thickness in the FIGURES that the applicants are able to show the cross hatching at all

Detailed description of the preferred embodiments

[00120] While the present invention is susceptible to being embodied in various forms, there is shown in the drawings a presently preferred embodiment hereinafter described. It should be understood that the present disclosure is to be considered as but one example of the invention, provided in sufficient detail for

those skilled in the art of dental devices to construct. It is not intended to limit the invention to the specific embodiments illustrated.

[00121] In the discussion below, several terms are used in a particular manner as explained in the following paragraphs.

[00122] An "edentulous gap" is defined herein as the space between a first tooth (or tooth substitute) and a second tooth (or tooth substitute) when all the in-between teeth are removed; or the space between a first tooth (or tooth substitute) and a tuberosity (or retromolar pad) when all the in-between teeth are removed.

[00123] A "terminal gap" is defined herein as that portion of an edentulous gap that is adjacent to an existing tooth, tooth substitute, retromolar pad, or tuberosity and within a distance of a single missing tooth of the existing tooth, tooth substitute, retromolar pad, or tuberosity.

[00124] An "edentulous void" is defined as a space formed between a ridge and the overlying mucosal tissue in a space previously occupied by a tooth.

[00125] A "terminal void" is defined herein as that portion of an edentulous void that is adjacent to an existing tooth, tooth substitute, retromolar pad, or tuberosity and within a distance of a single missing tooth of the existing tooth, tooth substitute, retromolar pad, or tuberosity.

[00126] "Terminal tooth" is defined as the still-existing tooth (or tooth substitute) that defines an end of an edentulous gap.

[00127] Referring now to the drawings, wherein like reference numerals refer to like parts throughout the several views, there is shown in **FIGURE 1** a tissue contourer **100** in the general form of a hollow cylinder **102** enclosed by generally hemispherical ends **104** and **106**. The cylindrical portion and the ends define an enclosed bladder **108** defined by a wall **110** of a generally constant thickness. The preferred wall thickness is between 0.01 and 1.0 mm. The length of the

bladder **108** is preferably between 2 and 250 mm , which will accommodate a range of edentulous gaps between adjacent teeth. The outer cylindrical diameter of the bladder is preferably between 2 and 20 mm.

[00128] The material from which the bladder is formed is self-sealing after it is pierced and the bladder filled. To fill the bladder, the operator inserts a thin tube such as a hypodermic needle through the wall of the bladder and introduces fluid into the bladder. This causes the bladder to expand. When the operator withdraws the thin tube from the bladder, the hole through which the tube passed self-closes and prevents significant fluid leakage from the bladder.

[00129] Preferably, at least 10% of the bladder surface is configured to self-seal when pierced and filled as described above. With an at least 10% surface area available for piercing and filling the bladder, the operator can pierce the mucosal tissue from any of several locations. These multiple sites permit the operator to inject fluid through the mucosal tissue into the bladder from several different locations, reducing the change for inflammation and infection resulting from the overuse of any particular location. In a more preferred embodiment, at least 25% of the bladder is self-sealing. In another preferred embodiment, the self-sealing portion of the bladder is located on an upper portion thereof.

[00130] **FIGURES 2**, **3** and **4** show another embodiment **200** of the tissue contourer **100** of FIGURE 1 that is constructed and configured in exactly the same manner as contourer **100**, but includes a specially configured region through which the operator insert fluid into the bladder. This region is called an "access port" or (more generally) a "port" herein.

[00131] In the embodiment of **FIGURES 2**, **3**, and **4**, tissue contourer **200** has a bladder **202** with an access port **204** on top of the bladder. The "top" of the bladder refers that portion of the surface of the bladder that faces toward the mucosal tissue and away from the maxilla or mandible when the tissue contourer is placed between the mucosal tissue and the bone of the mandible or maxilla.

[00132] Port **204** is provided to permit the operator to introduce fluid into (and preferably remove fluid from) the bladder. In the embodiment shown in **FIGURES 2, 3,** and **4**, port **204** includes a circular annulus **206** that is disposed in circular opening **208** located on top of bladder **202**.

[00133] Port **204** also includes a membrane **210** that extends across a central opening **212** of annulus **206** and closes it off. Membrane **210** is self-sealing. The operator can insert a hollow tube, such as a hypodermic needle, through the membrane and fill bladder **202**.

[00134] Membrane **210** prevents fluid from leaking out of the bladder through annulus **206**. By providing bladder **202** with a port having self-sealing or self-closing capabilities such as that provided by membrane **210**, fluid insertions into the bladder through the membrane **210** can be retained inside and prevented from leaking back out through the port. This permits a manufacturer to make bladder **202** out of different materials with different characteristics than might be required if the bladder material itself was required to be self-sealing. The wall thickness can thereby be made thinner, thicker or of different materials than the membrane **210**.

[00135] Annulus **206** has an outer flange **214** and an inner flange **216**. The outer flange **214** extends radially outward away from the longitudinal axis **218** of the annulus **206** across the outside surface of the bladder **202**. Flange **214** is generally parallel with the outer surface of the bladder in the region of the annulus **206**.

[00136] Inner flange **216** extends radially outward away from the longitudinal axis **218** of the annulus on the inside of the bladder and generally parallel with the inner surface of the bladder **202** in the region of the annulus **206**.

[00137] Port **204** is mounted generally flush with the surface of the bladder **202** and in a central longitudinal region thereof. It extends no more than 3 mm above the top surface of the bladder, more preferably no more than 2 mm, and

even more preferably no more than 1.25 mm. It should be recognized that the bladder **202** of **FIGURES 2, 3**, and **4** may be made in the same manner and with the same construction and characteristics as bladder **108** of **FIGURE 1**, and that bladder **108** may be made in the same manner and with the same construction and characteristics as bladder **202**.

[00138] Port **204** need not be located on the surface of the bladder, nor need it be located generally in a central longitudinal region of bladder **202**.

[00139] **FIGURES 5, 6** and **7** show an alternative embodiment of the tissue contourer of the foregoing **FIGURES** in which the port **204** has been moved to a different location that is adjacent the end of the bladder of the foregoing **FIGURES**, which is identified in **FIGURES 5, 6**, and **7** as bladder **500**. The only difference between the device of **FIGURES 5, 6**, and **7** and the devices of the foregoing **FIGURES** is in the location of the port, identified in **FIGURES 5, 6**, and **7** as port **502**.

[00140] Port **502** of the tissue contourer embodiment of **FIGURES 5, 6**, and **7**, has the same construction as port **204** of **FIGURES 2, 3**, and **4**. It is located differently, however. Port **502** also includes a tube **504** that extends from one end of bladder **500** at the point where the longitudinal axis of bladder **500** intersects the bladder itself. Tube **504** preferably has a length of between 1 and 25 mm.

[00141] Tube **504** permits access to the bladder **500** without the need to insert a needle or other filling device through the mucosal tissue and into the port, as would be the case using the embodiment of **FIGS. 2, 3**, and **4**. In this way, a tube extending through an opening or aperture in the mucosal tissue can fill the bladder 500.

[00142] Tube **504** is in fluid communication with both the annulus and the bladder to conduct fluid from the annulus to the bladder, and preferably to conduct it in the opposing direction as well. The length of the tube is preferably

between 1 and 10 mm, and is preferably of the same material as that used to form the bladder **500**.

[00143] **FIGURES 8**, **9**, **10** and **11** illustrate an alternative bladder end configuration for any tissue contourer bladder described or illustrated herein. This alternative bladder end is usable with any of the foregoing tissue contourers by configuring an end of the bladder with nosepiece **802**.

[00144] The nosepiece can either replace a bladder end and thereby become a part of the bladder itself, or it can be fixed to bladder end as an attachment thereto. It is preferably made of the same material as the bladder itself.

[00145] Referring to **FIGURE 8**, a bladder **800**, which is representative of any of the bladders described herein, includes a nosepiece **802** in the general form of a prolate hemispheroid that is flattened on one end. It has two sides, a first concave side **804** that faces the bladder and the probe, and a second convex side **806** that faces outward in the form of a prolate hemispheroid that is slightly flattened along its major axis.

[00146] The nosepiece has two hollows on the concave side. Hollow **808** is configured to receive (or to form) the end of the bladder, and hollow **810** is configured to receive the end of the probe.

[00147] To use the contourer, the operator inserts an insertion probe **812** into hollow **810** of nosepiece **802**. The operator then pushes the end of the probe together with tissue contourer into an incision that passes through the mucosal tissue. As the probe is forced into the incision and along the maxilla (or mandible, if the bladder is being used to contour mandibular mucosal tissue), the end of probe **812**, which is engaged in hollow **810**, pulls the tissue contourer along with it until the tissue contourer is drawn through the incision and between the bone and the overlying mucosal tissue. Once in this position, the probe can be withdrawn from the incision leaving the tissue contourer behind. The operator can then fill the tissue contourer with fluid and begin contouring the skin.

[00148] Note that probe **812** is disposed generally parallel and adjacent to the longitudinal extent of the tissue contourer bladder of **FIGURES 8** and **10**. It is in this parallel and adjacent orientation that the probe inserts the tissue contourer underneath the mucosal tissue.

[00149] In **FIGURES 8-11** the bladder is shown as having a hollow **810** that engages the probe tip. In alternative structures, the relations could be reversed, such as by having a hollow probe engage a protrusion located where hollow **810** is shown. In **FIGURES 8-11**, the probe engages the bladder end directly. In an alternative embodiment, a latch, catch, pin, clasp, link, clip, detent, or other releasable structure for engaging the probe and the bladder end may be provided to couple the two together.

Port Arrangements

[00150] **FIGURES 12** and **13** show an alternative port **1200** that may be used in any of the tissue contourers discussed herein. It includes an annular structure **1202** in fluid communication with a tissue contourer bladder **1204** (which may be any of the bladders illustrated or described herein). Annular structure **1202** includes a semi-rigid annulus **1206** defining a central longitudinal passageway **1208** across which is fixed a membrane **1210** that is self-sealing. Membrane **1210** extends across the central longitudinal opening of the annulus **1206** and seals the opening, thereby preventing fluid from escaping from the bladder.

[00151] A tube **1212** is coupled to annulus **1206** to conduct fluid from the annulus to the bladder. Annulus **1206** is fixed to the end **1209** of tube **1212** to limit and preferably block the flow of fluid therethrough, but to permit an operator to insert a hypodermic needle or other tubular structure therethrough to fill the bladder with fluid.

[00152] **FIGURES 14**, **15** and **16** show an alternative port **1400** that differs from the arrangement of **FIGURES 12-13** in the structure of the annulus and the arrangement of the membrane.

[00153] Port **1400** includes an annular structure **1402** in fluid communication with a tube **1404** that is in fluid communication with a tissue contourer bladder (not shown). Port **1400** functions to reduce or prevent the flow of fluid out of the bladder. The annular structure **1402** is coupled to and in fluid communication with both tube **1404** and bladder (not shown) to conduct the fluid that fills the bladder therebetween.

[00154] The annular structure **1402** includes a semi-rigid annulus **1406** defining a central longitudinal passageway **1408** across which is fixed a membrane **1410** that is self-sealing. Membrane **1410** is circular and extends perpendicular to and across passageway **1406** to seal the passageway, thereby limiting or preventing fluid from escaping from the bladder.

[00155] The annulus includes upper and lower inwardly extending flanges **1412** and **1414**, respectively, to which the membrane and the tube are attached. The membrane **1410** is bonded to the inside surface of flanges **1412** and the tube is bonded to the inside surface of flange **1414**.

[00156] **FIGURE 17** illustrates a prior art syringe **1700** used to fill any of the ports having self-sealing membranes described herein. The syringe includes a needle **1702** that is mounted to the syringe body **1704**. Needle **1702** has a point **1706** that is configured to pierce and penetrate the self-sealing membranes of the ports shown herein. It is also configured to pierce any self-sealing bladder of a tissue contourer described herein.

[00157] **FIGURES 18** and **19** show another alternative port **1800** that may be used in any of the tissue contourers discussed herein. It includes an annular structure **1802** in fluid communication with a bladder (not shown). A tube **1806** is coupled to and in fluid communication with both annular structure **1802** and bladder to conduct fluid to and from the bladder.

[00158] Annular structure **1802** has an inwardly extending circular valve seat **1808**. Structure **1802** includes a circular planar valve element **1810** having a

diameter that is greater than that of seat **1808**. Valve element **1810** is configured to abut seat **1808** and to block off fluid flow through tube **1806**, thereby preventing fluid from leaking out of the bladder to which the tube is connected.

[00159] A spring **1812** is disposed within annular structure **1802** with one end abutting the annular structure and the other end abutting valve element **1810**. The spring is configured to press valve element **1810** against seat **1808**. The spring is preferably a metallic coil compression spring, slightly compressed when valve element **1810** is closed in order to keep the valve element sealed against seat **1808**. The spring may also be made of plastic. Rather than being separately manufactured and inserted into the annular structure, the spring can be formed integrally with the annular structure. It may also be configured as a leaf spring or a tension spring.

[00160] Tube **1806** is coupled to and in fluid communication with a tissue contourer bladder, which may be any of the tissue contourer bladders described herein.

[00161] Annular structure **1802** includes an upper portion **1814** that is configured to mechanically engage a syringe (**FIG. 20**) or other structure for inserting fluid into the port to the tissue contourer to which it is coupled. In the preferred embodiment, the upper portion **1814** of the valve body has a threaded internal surface **1816** that engages a similar threaded outer surface **2000** of syringe **2002** (**FIG. 20**). To couple syringe **2002** and annular structure **1802**, the operator inserts the threaded outer surface **2000** into a cylindrical hole **1818** in upper portion **1814**. The operator then twists syringe **2002** with respect to the upper portion **1814** until the threads on the syringe **2002** and the annular structure **1802** mutually interengage to create a leak-resistant joint between the syringe and the port **1800**.

[00162] The threaded portions of the valve body and the syringe are preferably provided with a thread pitch and taper sufficient to engage and seal one against the other after five revolutions of the syringe with respect to the valve body or

less, more preferably after three revolutions or less, and even more preferably after two revolutions or less.

[00163] **FIGURES 21** and **22** illustrate the port of **FIGURES 18** and **19** having a modified annular structure **2102**. The modified annular structure **2102** of port **2100** is configured to accommodate a movable spherical ball valve element **2104**. Valve element **2104** abuts and seals against valve seat **2106** formed on an interior surface of annular structure **2102**. Other than the replacement of the valve element **1810** and spring **1812** with the ball valve element **2104**, port **2100** shown in **FIGURES 21** and **22** is the same in all respects as port **1800** shown in **FIGURES 18** and **19**.

Bladder Arrangements

[00164] The bladders of the tissue contourers shown in the above examples are generally configured as elongated circular cylinders having generally hemispherical ends. Bladders configured in this manner are suitable for general use. Other configurations of these bladders are possible and indeed recommended for particular applications to expand tissue.

[00165] **FIGURES 23-60** illustrate several of these alternative bladders that are constructed somewhat differently from the bladders identified above. These bladders differ from the bladders illustrated above in the stiffness, thickness and relative elasticity of their walls, as well as their overall geometry and shape, discussed in more detail below. In each of these embodiments, at least one wall and often more than one are stiffer than other walls as indicated by their ability to resist bending or expanding more than other walls. This stiffness may be provided by making walls out of different materials, having different thicknesses or both.

[00166] As in the case of the bladders shown and discussed above, they also can be made of the same materials and may be equipped with a port such as any of the port arrangements described above.

[00167] **FIGURES 23-26** show the first of these alternative bladder arrangements. In these **FIGURES,** the bladder **2300** is an elongated body, having two opposing ends **2302, 2304**, each end having a smaller area than the elongated sides **2306, 2308, 2310**, and **2312**.

[00168] The bladder is shown (**FIG. 24**) in a cross-section that is taken perpendicular to the longitudinal axis **2314** of bladder **2300**. In this cross-section, the bladder **2300** is a polygon having four sidewalls or sides **2306, 2308, 2310,** and **2312**. Two of those cross-sectional sides, the top side **2310** and the bottom side **2312**, are parallel. Two other sides, the left side **2306** and the right side **2308**, are also parallel. The top and bottom sides **2310, 2312** are of equal length. The left and right sides **2306, 2308** are of equal length. Each of the four side walls **2306, 2308, 2310, 2312** are disposed at right angles to their adjacent sidewalls.

[00169] Ends **2302, 2304** of the bladder are polygons and have four edges where ends **2302, 2304** meet their adjacent sidewalls **2306, 2308, 2310, and 2312**. The edges where end **2304** meets its sidewalls **2306, 2308, 2310**, and **2312** are identified as items **2322, 2324, 2326**, and **2328**.

[00170] The top and the bottom edges **2326** and **2328** of end **2304** are parallel. The left and the right edges **2322** and **2324** of end **2304** are also parallel. The ends **2302, 2304** are parallel to each other, and are preferably polygons, preferably regular polygons, preferably rectangles, and preferably squares.

[00171] **FIGURES 25** and 26 illustrate the manner in which bladder **2300** is inflated to increase its size. In **FIGURES 25** and **26,** the bladder expands in a central region by stretching the four sides **2306, 2308, 2310**, and **2312**. When the bladder is inflated, these sides stretch and expand outward.

[00172] As the bladder is inflated, the walls are configured to expand such that middle region **2330** of bladder **2300** becomes generally circular in longitudinal

cross-section and the edges between each adjacent side **2306**, **2308**, **2310**, and **2312** flatten.

[00173] The walls are also configured to expand during inflation such that the middle region **2330** has the greatest girth and the greatest increase in size. The girth of the bladder preferably decreases as one moves from the central region **2330** toward each end **2302**, **2304**.

[00174] The walls of bladder **2300** are also configured such that successive longitudinal cross-sections of inflated bladder **2300** (as shown in **FIGURES 25** and **26**) are successively more square and the edges between adjacent sides **2306**, **2308**, **2310** and **2312** more pronounced as one moves along bladder **2300** from central region **2330** toward either opposing end **2302**, **2304**.

[00175] In **FIGURES 25** and **26**, the ends **2302**, and **2304** are configured to flex less than the sides, therefore causing them to remain generally flat as compared to sides **2306**, **2308**, **2310**, and **2312** when the bladder is inflated. As bladder **2300** is inflated, the ends neither substantially stretch, nor increase in size (as compared to adjacent sides **2306**, **2308**, **2310** and **2312**) and maintain substantially their original dimensions (as compared to adjacent sides **2306**, **2308**, **2310** and **2312**) even after the bladder is inflated.

[00176] One way of making the ends stiffer such that they deflect less than sides **2306**, **2308**, **2310**, and **2312** when the bladder is inflated is to make the ends **2302**, **2304** thicker than the sides. Increased stiffness may also be provided by making ends **2302**, **2304** of a material different than that of sides **2306**, **2308**, **2310**, **2312**, a material having a greater modulus of elasticity than that of the sides. The material of which the ends are constructed may be filled or reinforced with particles, threads or fibers of a material having a higher modulus of elasticity than that of sides **2306, 2308, 2310, and 2312**.

[00177] In some cases, it may be desirable to employ a tissue contourer that is configured to enlarge or expand on one side more than another. For example, a

bladder providing greater expansion of its top side than its left side, right side and bottom, or of its top, left and right sides than its bottom side. With bladders configured in this manner, the bladder's bottom side (which is installed adjacent to bone of the mandible or maxilla) would remain in a more accurate position, and be less inclined to slip when the patient chews, for example.

[00178] A first example of such a heterogeneously expanding tissue contourer bladder can be seen in **FIGURES 27** (side view) and **28** (cross-section), which shows the tissue contourer in is expanded condition. In its unexpanded condition, it would appear identical to the bladder of **FIGURES 23** and **24**.

[00179] Bladder **2700** of **FIGURES 27** and **28** differs from the bladder **2300** of **FIGURES 23, 24, 25** and **26** in one respect only: three of its longitudinally extending left, bottom and right sides **2702, 2704, 2706** are constrained to expand and flex outward less than the longitudinally extending top side **2708** when the bladder is inflated.

[00180] The greater relative stiffness of sides **2702, 2704, 2706** is provided by making sides **2702, 2704, 2706** thicker than side **2708**. It may also be provided by making sides **2702, 2704, and 2706** of a material different than that of side **2708**, a material that, for example, has a greater modulus of elasticity than the modulus of elasticity of sides **2702, 2704**, and **2706**. The material used on sides **2702, 2704, 2706** may also be reinforced, such as by embedding fibers, threads or particles in the material of which they are comprised.

[00181] **FIGURES 29-33** show another embodiment of the tissue contourer identified as item **2900**. Bladder **2900** is generally in the form of an elongate cylinder **2902** having relatively flat ends **2904** and **2906**. In cross-section, cylinder **2902** is not a polygon. It is a closed conic section, as shown in the cross-section of **FIGURE 31**. Preferably the conic section is a circle. **FIGURE 31** also illustrates another characteristic of bladder **2900**, that the wall thickness of the bladder is constant as one moves in a circumferential direction.

[00182] Cylinder **2902** is a right circular cylinder and has a constant cross-sectional area. Ends **2904** and **2906** of bladder **2900** therefore have the same area and are both conic sections, preferably circles. Ends **2904** and **2906** are also both preferably parallel, to each other.

[00183] **FIGURES 32** and **33** illustrate the bladder **2900** of **FIGURES 29, 30** and **31** after inflation. The bladder **2900**, when filled with fluid, expands along its length to form the cylindrical shape shown in **FIGURES 32** and **33**. In this configuration, the cylinder has a greater cross-sectional area at the center portion **3200** of its longitudinal axis **3202** than it does at each end **2904, 2906**. The cross-sectional profile is circular.

[00184] **FIGURES 34A, 34B, 35, 36**, and **37** illustrate an alternative tissue contourer bladder **3400** having a planar lower wall **3402** and a convex upper wall **3404** bonded to the lower wall **3402** at the distal edges of the upper and lower walls to form a generally lens-shaped bladder.

[00185] The lower wall **3402** is more rigid than the upper wall **3404**. When bladder **3400** is inflated, upper wall **3404** expands and moves upward, increasing in size. At the same time, the lower wall **3402** maintains its planar area and planar shape constant.

[00186] In plan view, the shapes of both the upper and lower walls are circular as shown in **FIGURE 35**. This shape does not change when the bladder is inflated, as best seen in **FIGURE 36** and (in cross-section) **FIGURE 37**.

[00187] In **FIGURES 36** and **37**, the curved dashed line **3406** represents the original, unexpanded position of the upper surface. The curved solid line represents the position of the upper wall after the bladder has been filled and the upper wall has been distended and expanded.

[00188] **FIGURES 38-41** illustrate another configuration of the tissue contourer bladder in which the bladder **3800** has two hemispherical ends **3802** and **3804** that are coupled to an elongated circular cylindrical portion **3806**. In this example,

when bladder **3800** is filled, the cylindrical portion **3806** is filled; it expands generally uniformly, maintaining a relatively constant diameter over substantially all of its length. In a similar fashion, the hemispherical ends also expand uniformly maintaining their hemispherical shape as the size of the tissue contourer bladder increases.

[00189] This increase in size is apparent from an examination of **FIGURES 40** and **41** (which is a cross-section of **FIGURE 40**). Dashed line **3808** in **FIGURES 40** and **41** represents the outer surface of the bladder before it is filled and expanded. The solid line in **FIGURE 40** represents the outside surface of that same bladder **3800** after it has been filled and expanded. Note that the diameter of cylindrical portion **3806** is preferably constant along its length.

[00190] The overall length of the bladder has increased as well. This increase is length is provided by the expansion and outward distension of ends **3802** and **3804**.

[00191] **FIGURES 42-45** show another embodiment **4200** of a tissue contourer bladder having an elongated shape with generally rounded ends, a flat bottom and a rounded upper surface.

[00192] The bladder **4200**, shown in cross-section in **FIGURE 43**, has a bottom wall **4202** of relatively constant thickness and a top wall **4204** of relatively constant thickness as well. The two walls meet at their distal edges where they are joined together to create the enclosed bladder shape.

[00193] The top wall **4204** is convex, and arches upward across the top of the bottom wall **4202**. The length of bladder **4200** is greater than its width.

[00194] **FIGURES 44** and **45** illustrate the same side view and the same cross-sectional view of bladder **4200** that **FIGURES 42** and **43** illustrate. **FIGURES 44** and **45** illustrate bladder **4200** in its expanded or distended condition after it has been filled with fluid.

[00195] In **FIGURES 44** and **45**, the original shape of the top wall of the bladder is shown as dashed line **4206**. The new shape and position of the top wall of the bladder is shown as a solid line.

[00196] A comparison of the two illustrates that the bottom wall of the bladder is rigid and planar even after the bladder has been filled with fluid. It is stiff enough to prevent the bladder from increasing in length or in width as bladder **4200** is filled with fluid and expands.

[00197] **FIGURES 46**, **47**, **48**, and **49** illustrate alternative tissue contourer bladder configurations **4600**, **4700**, **4800**, and **4900** that differ from the bladders of **FIGURES 34-45** in one respect only: their shape in top or plan view. Like the embodiments of **FIGURES 34-45**, bladders **4600**, **4700**, **4800**, and **4900** have flat bottom walls and curved top walls **4602**, **4702**, **4802**, and **4902** that expand or distend upward when the bladders are filled with fluid. They also have the same planar bottom wall construction that is stiff and does not distend or expand when the bladder is filled with fluid as the top wall expands.

[00198] The bladder of each of **FIGURES 46**, **47**, **48** and **49** is intended for insertion in the mouth of a patient in a particular orientation given by the letters F (facial), L (lingual), D (distal) and M (mesial). Thus, the bladders of **FIGURES 46**, **47** and **48** have a greater lingual-facial width at their distal end than they have at their mesial end.

[00199] This difference in width provides more tissue contouring for the distal teeth (e.g. cuspids) than it does for the mesial teeth (e.g. incisors) where the crest curvature is greatest.

[00200] Another feature of the bladders of **FIGURES 46** and **47** is the curvature of the bladder in the distal-mesial direction. The bladder curves to follow the crest. This insures that the bladder will contour the tissue at the appropriate location.

[00201] Bladder **4800** of **FIGURE 48** has a broader distal end and narrower mesial end, but lacks the curvature shown in the examples of **FIGURES 46** and **47**. This bladder, in fact, is generally straight and does not curve along its distal/mesial axis. It is intended for molar/premolar contouring.

[00202] Bladder **4900** of **FIGURE 49** is configured to be broader in the middle of its length in the facial direction and than it is at either end. This configuration would be particularly beneficial when dealing with severe erosion. In cases such as these, the erosion is most severe in the central region of the edentulous span and the tissue contourer must have a greater thickness in the ventral region raise the receded gum tissue farther to its original gum line.

Wall thickness

[00203] Varying the thickness of the bladders can provide increased stiffness and reduced expandability in different regions of the bladder itself. This is important where one desires more tissue expansion in one region of the mucosal tissue and less in another.

[00204] When a tissue contourer with a varying wall thickness is filled with fluid, the thicker regions do not expand as much as the thinner regions. The regions that expand more place additional pressure on the mucosal tissue, which causes it to expand more.

[00205] More tissue expansion is provided in the portions of mucosal tissue that surround the thinner-walled regions of the tissue contourer bladder than those that surround the thicker-walls regions of the tissue contourer bladder.

[00206] Thus, if one wants to encourage greater tissue expansion in the region of a particular missing tooth, for example, one would employ a tissue contourer having thinner walls adjacent to the region of the missing tooth.

[00207] Due to the thinner walls in this region, the contourer would expand to a greater degree and additional expanded tissue would be formed to surround this enlarged region, as desired.

[00208] Several embodiments of tissue contourer bladders having different wall thicknesses to contour tissue in specific regions are illustrated in **FIGURES 50-60**.

[00209] **FIGURES 50** and **51** illustrate a tissue contourer bladder **5000** having the same overall shape as the contourer of **FIGURES 34-37** above. It has a bottom wall **5002** and top wall **5004** that differ in thickness. The top wall **5004** is thinner than the bottom wall, causing bladder **5000** to expand and distend to a greater degree on its upper surface than on its lower surface.

[00210] When bladder **5000** is filled with fluid, its bottom wall **5002** will remain relatively flat and will not increase substantially in size, while its thinner top surface **5004** will expand and increase in size.

[00211] **FIGURES 52** and **53** illustrate another tissue contourer bladder **5200** in which expansion in controlled by varying the wall thickness. The tissue contourer bladder shown in cross-section in **FIGURES 52** and **53** has the same shape and configuration as that of **FIGURES 27** and **28** but provides the controlled expansion of top wall **5202** (i.e. wall **2708** in **FIGURES 27** and **28**) by making top wall **5202** thinner than the sidewalls **5204** and **5206**, and bottom wall **5208**.

[00212] **FIGURES 54-56** illustrate another embodiment of the tissue contourer bladder **5400** in which the expansion and distension of the bladder is concentrated in its central region by making the bladder thinner-walled along its length than at its ends. In this example, bladder **5400** has the same overall shape as the bladder of **FIGURE 29**: that of an extended right circular cylinder. The ends **5402** and **5404** of bladder **5400** are flat and at right angles to the cylindrical length of bladder **5400**. They are thicker than the cylindrical portion **5406** of

bladder **5400** and therefore resist expansion and outward distention when the bladder **5400** is filled.

[00213] The effect of this increased thickness at the ends of the bladder **5400** is illustrated in **FIGURE 56**, which shows the shape of bladder **5400** when it is filled with fluid. Bladder **5400** expands, but the expansion occurs predominately in its central cylindrical portion **5406** and much less at each end **5402** and **5404**.

[00214] **FIGURES 57** and **58** illustrate an alternative tissue contourer bladder **5700** having the same shape as that of the bladder of **FIGURES 38-41**, but with alternative wall thicknesses that control its expansion in a different manner.

[00215] In the example of **FIGURES 38-41**, the bladder has a relatively constant wall thickness, causing the bladder to expand with relatively constant cylindrical diameter along its length and to have hemispherical ends with generally the same radius.

[00216] In **FIGURE 57,** bladder **5700** is shown in an unexpanded configuration before fluid is introduced. The ends of the bladder are thicker to provide more stiffness and rigidity to bladder ends **5702** and **5704**, thereby constraining and limiting their expansion. The cylindrical sidewall **5706** of bladder **5700** has thinner walls to provide enhanced expansion of the cylindrical sidewall **5706**.

[00217] **FIGURE 58** illustrates the effect of this configuration. In **FIGURE 58**, the bladder **5700** of **FIGURE 57** has been filled with fluid and the central cylindrical sidewall **5706** has expanded significantly more than the ends **5702** and **5704**.

[00218] **FIGURES 59** and **60** illustrate a bladder **5900** having the inverse expansion relationship between the central region and the ends as compared to that shown in **FIGURES 57** and **58**. In **FIGURES 59** and **60**, the desired tissue expansion is at the ends of the bladder **5900**. For this reason the wall thicknesses of the ends **5902, 5904** of bladder **5900** in **FIGURES 59** and **60** is reduced and the wall thickness of the central cylindrical portion **5906** of bladder

5900 is increased. The thickness of central cylindrical region **5906** is greater than the ends **5902** and **5904**.

[00219] By making the central cylindrical region **5906** thicker than ends **5902** and **5904**, expansion and distention of the bladder occurs largely at ends **5902** and **5904**, as shown in **FIGURE 60**, than in the central cylindrical region **5906** which illustrates the bladder **5900** after it has been filled with fluid and expanded.

[00220] **FIGURES 61A, 61B, 61C, 61D,** and **61E** show the different surface textures that may be applied to any of the tissue contourer bladders described or illustrated herein. Each of **FIGURES 61A-61E** show a different texture that can be provided on the bladders to provide a better grip on the tissue and bone inside the submucosal or subperiostial void in which they are inserted. While each of the different textures is shown as extending only over a narrow band along the length of the tissue contourer bladder, this arrangement is for ease of illustration. In the preferred embodiment, any of the textures will extend substantially the entire length of a bladder as the textures do as a whole in **FIGURES 61A-61E.**

[00221] The first texture illustrated is shown in **FIGURE 61A**, which has a texture comprised of a pattern of surface irregularities **6100** shown here as generally circular protrusions or concavities disposed on a surface **6102** of a tissue contourer bladder **6104**. The irregularities **6100** are preferably arranged on the surface to form polygons, preferably regular polygons, more preferably quadrilaterals, and more preferably squares, as shown here. While the pattern is shown here covering one fifth of the surface at the leftmost end, it may cover as much as the entire surface, excluding the other textures. It is preferably disposed on one side of the bladder, as shown here. In an alternative embodiment, it may extend around the circumference of the bladder.

[00222] The second texture illustrated is shown in **FIGURE 61B**, which has a texture comprised of a pattern of surface irregularities **6106** shown here as generally oval, rounded elongate, or lens-shaped protrusions or concavities disposed on a surface **6102** of a tissue contourer bladder **6104**. The irregularities

6106 are preferably arranged on the surface to form polygons, preferably regular polygons, more preferably quadrilaterals, and more preferably squares, as shown here. While the pattern is shown here covering about one-fifth of the surface adjacent the left end of the bladder, it may cover more of the surface, even the entire surface. It is preferably disposed on one side, as shown here. In an alternative embodiment, it may extend around the circumference of the bladder.

[00223] The irregularities **6106** are preferably laid end-to-end, such that the termination point of one irregularity is the beginning of another. The irregularities are preferably overlaid to define what appears to be a webwork or weave of irregularities on the surface **6102**.

[00224] **FIGURE 61D** differs from **FIGURE 61B** in that the irregularities **6110** of **FIGURE 61D** are elongated polygons and not elongated ovals as irregularities **6106** are. In all other respects, the patterns of **FIGURES 61B** and **61D** are the same.

[00225] Another alternative texture is shown in **FIGURE 61C**, in which at last some of the irregularities **6108** are arranged at right angles to each other, with a first plurality arranged diagonally to the length of the bladder and a second plurality also arranged diagonally to the length of the bladder but wherein the first and second pluralities are arranged at right angles to one another. Other than this diagonal arrangement, the irregularities and textures of **FIGURES 61B** and **FIGURE 61C** are the same.

[00226] **FIGURE 61E** differs from **FIGURE 61C** in that the irregularities **6112** of **FIGURE 61E** are elongated polygons and not elongated ovals as irregularities **6108** are. In all other respects, the patterns of **FIGURES 61C** and **61E** are the same.

[00227] **FIGURES 62A-62C** illustrate three possible arrangements of the irregularities of **FIGURES 61A-61E** in the wall of bladder **6104**. **FIGURES 62A-C** are three different alternative cross-sections of the surfaces of the bladders

shown in **FIGURES 61A-61E**, wherein the cross-sections taken generally through the irregularities themselves.

[00228] In **FIGURE 62A**, the irregularities **6200**, which show the cross-sectional profile of the irregularities **6100, 6106, 6108, 6110**, and **6112** shown in **FIGURES 61A-E**, all extend inwardly, forming concavities **6204** in the surface **6102** of bladder **6104** (also shown in **FIGURES 61A-61E**). Irregularities **6200** preferably have curved and generally hemispherical bottom.

[00229] In **FIGURE 62C**, which illustrates another alternative arrangement of the irregularities of **FIGURES 61A-61E**, irregularities **6206**, which show an alternative cross-sectional profile of the irregularities **6100, 6106, 6108, 6110**, and **6112** shown in **FIGURES 61A-E**, include a combination of inwardly extending concavities **6208** and outwardly extending protrusions **6210** that are interspersed with one another in the surface **6102** of bladder **6104**. Irregularities **6208** and **6210**, both protrusions and concavities are preferably curved and generally hemispherical in cross-section.

[00230] In **FIGURE 62B**, which illustrates a third alternative arrangement of the irregularities of **FIGURES 61A-61E**, irregularities **6212**, which may be any of the irregularities **6100, 6106, 6108, 6110**, and **6112** shown in **FIGURES 61A-E**, comprise outwardly extending protrusions **6214** in the surface **6102** of bladder **6104**. Irregularities **6212** preferably have curved and generally hemispherical top surfaces in cross-section.

[00231] **FIGURES 63-65** illustrate an alternative tissue contourer bladder having a generally vertically-extending wall that defines a passageway therethrough.

[00232] In plan view (**FIG. 63**) bladder **6300** has a first end **6302**, a second end **6304**, a top surface **6306** and a bottom surface **6308**. Each end **6302** and **6304** is preferably rounded in plan view. Top surface **6306** is generally rounded at its edges and extends across and above a preferably planar bottom surface

6308. A passageway **6310** extends through the bladder **6300** from the top surface to the bottom surface. With this passageway, the bladder is in the form of a hollow torus having a single hole passing therethrough.

[00233] The passageway **6310** is generally circular and has a diameter of between 2.5 and 10.0 mm. It is sized to receive dental implant, permitting them to be inserted into the bone and extend upward through the passageway.

[00234] In **FIGURES 66-67** a tissue contourer **6600** is shown having contours on its upper surface that imitate the contours of a healthy gum line. These contours include contouring projections **6602** that extend upward at locations corresponding to papilla. Between each of these projections are valleys or recesses **6604** that are located where missing teeth are to be replaced. The spacing of these valleys (and hence the spacing of the projections) is preferably between 2 and 10 mm. The height of the projections is preferably between 1 and 5 mm, from peak to valley.

[00235] **FIGURES 68** and **69** show an alternative tissue contourer **6800** to that of **FIGURES 66-67**. The contourer of **FIGURES 68** and **69** has a bladder **6802** with a plurality of generally vertical passageways **6804** extending therethrough. These passageways extend from the top surface **6806** to the bottom surface **6808** and are configured to receive dental implants. In all other respects, the contourer is that of **FIGURES 66** and **67**. Passageways **6804** have generally parallel longitudinal axes and are arranged in a line that curves to follow the crest of the mandible and maxilla. The longitudinal axis of each passageway is preferably disposed one tooth-space (e.g. between 2 and 10 mm) from the longitudinal axis of the adjacent passageways. The longitudinal axes of the passageways on each end of the contourer are preferably spaced one-half of a tooth-spacing from the end.

[00236] **FIGURES 70** and **71** illustrate an alternative port arrangement for any of the tissue contourer bladders described or illustrated herein in which two bladders **7000, 7002** are coupled to a common port **7004** to be jointly and

simultaneously filled and emptied. Bladders **7000** and **7002** may be any of the bladders described or illustrated herein. Port **7004** includes a self-sealing membrane **7006** that extends across the opening of annulus **7008**. Annulus **7008**, in turn is in fluid communication with tube **7010**, which has two branches **7012** and **7014** that are in fluid communication with bladders **7000** and **7002**.

[00237] The operator can insert fluid through membrane **7006** using one of the syringes or needles described herein. This fluid will traverse both branches **7012** and **7014** and respectively fill bladders **7000** and **7002**, respectively.

<u>**Dimensions of the contourer**</u>

Successfully contouring mucosal tissue depends upon several factors, including (1) the number of teeth in the edentulous gap, (2) the particular type and contour of the teeth missing in the edentulous gap, (3) the particular devices used to replace the missing teeth and bone, for example, a bone graft, mesh scaffolding or other subperiostial or submucosal structures, (4) the degree of mandibular or maxillary bone erosion, (5) the amount of suturing, and (6) the type of sutures that are used.

[00238] Experience and analysis has revealed that determining the proper bladder is not an easy task, in view of the non-linearity of certain other phenomena as well, such as the width of the edentulous gap. For example, as the width of the edentulous gap increases, the degree of bone erosion is accentuated in the medial portions of the gap. The medial portions, lacking the influence of adjacent teeth, erode at a much greater rate that is much more rapid than the erosions at the ends of the edentulous gap. Further complicating the configuration of the tissue expander are differences between anterior erosion and posterior erosion. Erosion is more pronounced in the anterior portion of the mandible and maxilla than it is in the posterior portions, either left lateral or right lateral. Thus, a tissue expander appropriate for crafting replacements to missing anterior teeth is preferably configured differently than a tissue expander appropriate for crafting replacements to missing posterior teeth.

[00239] There are three primary differences between tissue contourers, including differences in volume, differences in thicknesses, and differences in length. Of these three, two are perhaps the most significant: differences in volume and differences in length. "Length" in this context means installed length – i.e. the length of the tissue contourer when it is installed in an edentulous gap.

[00240] These differences are illustrated in the following tables, which distinguish tissue contourers by their length and their volume.

[00241] Table 1 lists the preferred range of lengths and volumes of tissue contourers used in cases of moderate maxillary and mandibular atrophy.

[00242] Table 2 lists the preferred range of lengths and volumes of tissue contourers used in cases of severe maxillary and mandibular atrophy.

[00243] Table 3 lists the preferred range of lengths and volumes of tissue contourers used in cases of extreme maxillary and mandibular atrophy.

[00244] The tables use a particular notation to indicate the specific edentulous gap they are intended to fill. The lengths of the contourers vary with the specific gap they are intended to fill. The volumes vary as well. Furthermore, the volume of each tissue expander varies with the type and degree of osseous atrophy. Table 1 identifies the characteristics of tissue contourers appropriate for contouring gaps of from one to eight teeth at different locations, and with moderate osseous atrophy. Table 2 identifies the characteristics of tissue contourers appropriate for contouring gaps of from one to eight teeth at different locations, and with severe osseous atrophy. Table 3 identifies the characteristics of tissue contourers appropriate for contouring gaps of from one to eight teeth at different locations, and with extreme osseous atrophy

[00245] Each row in the tables lists an edentulous gap, followed by a range of acceptable volumes and a range of acceptable lengths for the tissue contourer configured for that gap. The volume ranges are expressed in milliliters as maximum volumes (Vmax) and corresponding minimum volumes (Vmin) that

define that preferred range. The length ranges are likewise expressed in millimeters as maximum and minimum lengths (Lmax, Lmin) that define that preferred range.

[00246] The edentulous gaps the tissue contourer is intended to contour are expressed in terms of the teeth that are missing in each gap. The teeth are identified using the Universal Dental Numbering System, in which each tooth, both maxilla and mandible, has a number of between 1 to 32, depending upon its location in the mouth of the patient.

[00247] The first row of Table 1 represents the preferred volume and length of a tissue contourer intended to contour tissue in an edentulous gap comprising a missing tooth 5, a missing tooth 12, a missing tooth 21, or a missing tooth 28. Teeth 5 and 12 are first maxillary premolars. Teeth 21 and 28 are first mandibular premolars. The second row of Table 1 represents the preferred volume and length of a tissue contourer intended to contour tissue in any of four edentulous gaps, the gaps comprising missing teeth 4 and 5, or missing teeth 12 and 13, or missing teeth 20 and 21, or missing teeth 28 and 29. These edentulous gaps correspond to both maxillary and mandibular first and second premolars.

Table 1
(Tissue Contourers used in Cases of Moderate Atrophy)

Posterior Region: Mandible & Maxilla

edentulous gap	Vmin	Vmax	Lmin	Lmax
5, 12, 21, 28	0.5	1.5	6.9	8.0
4-5, 12-13, 20-21, 28-29	1.0	3.0	13.6	15.8
3, 14, 19, 30	0.5	2.0	10.0	12.0
2-3, 14-15, 18-19, 30-31	1.0	4.0	19.0	22.4
3-5, 12-14, 19-21, 28-30	1.5	6.0	23.6	27.8
2-4, 13-15, 18-20, 29-31	1.0	4.0	25.9	30.4
2-5, 12-15, 18-21, 28-31	3.0	8.0	32.9	38.2

Anterior Region: Mandible

edentulous gap	Vmin	Vmax	Lmin	Lmax
22, 27	0.5	1.5	6.7	8.0
23, 24, 25, 26	0.5	1.0	5.0	6.5
22-23, 26-27	1.0	3.0	13.7	14.5
22-24, 25-27	1.5	5.0	18.7	21.0
24-25	1.0	2.0	10.0	13.0
22-25, 24-27	2.0	6.0	23.7	27.5
22-26, 23-27	2.5	7.0	28.7	34.0
22-27	3.0	8.5	35.4	42.0

Anterior Region: Maxilla

edentulous gap	Vmin	Vmax	Lmin	Lmax
6, 11	0.5	1.5	7.5	9.0
7, 10	0.5	1.0	6.4	7.0
8, 9	0.5	1.5	8.5	10.0
6-7, 10-11	1.0	3.0	13.9	16.0
6-8, 9-11	1.5	5.0	22.4	26.0
7-8, 9-10	1.0	2.5	14.9	17.0
6-9, 8-11	2.0	6.0	30.9	36.0
6-10, 7-11	2.5	7.0	37.3	43.0
6-11	3.0	8.5	44.8	52.0

Transitional Region: Mandible

edentulous gap	Vmin	Vmax	Lmin	Lmax
21-24, 25-28	2.0	6.5	25.6	29.0
20-24, 25-29	2.5	8.0	32.3	36.8
19-24, 25-30	3.0	10.0	42.3	48.8
18-24, 25-31	4.0	12.0	51.0	71.2
18-22, 27-31	3.5	9.5	41.0	58.2
18-23, 26-31	3.5	10.5	46.0	64.7
21-22, 27-28	1.0	3.0	13.6	16.0
21-23, 26-28	1.5	4.0	18.6	22.5

20-22, 27-29	1.5	4.5	20.3	23.8
20-23, 26-29	2.0	5.5	25.3	30.3
19-22, 27-30	2.0	6.5	30.3	35.8

Transitional Region: Maxilla

edentulous gap	Vmin	Vmax	Lmin	Lmax
5-8, 9-12	2.0	6.5	29.3	34.0
4-8, 9-13	2.5	8.0	36.0	41.8
3-8, 9-14	3.0	10.0	46.0	53.8
2-8, 9-15	4.0	12.0	55.0	64.2
2-6, 11-15	3.5	9.5	40.1	47.2
2-7, 10-15	3.5	10.5	46.5	54.2
5-6, 11-12	1.0	3.0	14.4	17.0
5-7, 10-12	1.5	4.0	20.8	24.0
4-7, 10-13	2.0	5.5	27.5	31.8
3-7, 10-14	2.5	7.5	37.5	43.8

Table 2

(Tissue Contourers used in Cases of Severe Atrophy)

Posterior Region: Mandible & Maxilla

edentulous gap	Vmin	Vmax	Lmin	Lmax
5, 12, 21, 28	0.75	2.25	6.90	8.00
4-5, 12-13, 20-21, 28-29	1.50	4.50	13.60	15.80
3, 14, 19, 30	0.75	3.00	10.00	12.00
2-3, 14-15, 18-19, 30-31	2.25	9.00	19.00	22.40
3-5, 12-14, 19-21, 28-30	2.25	9.00	23.60	27.80
2-4, 13-15, 18-20, 29-31	1.50	6.00	25.90	30.40
2-5, 12-15, 18-21, 28-31	4.50	12.00	32.90	38.20

Anterior Region: Mandible

edentulous gap	Vmin	Vmax	Lmin	Lmax
22, 27	0.75	3.00	6.70	8.00
23, 24, 25, 26	0.75	1.50	5.00	6.50
22-23, 26-27	1.50	4.50	13.70	14.50
22-24, 25-27	2.25	7.50	18.70	21.00
24,-25	1.50	3.00	10.00	13.00
22-25, 24-27	3.00	9.00	23.70	27.50
22-26, 23-27	3.75	10.50	28.70	34.00
22-27	4.50	12.75	35.40	42.00

Anterior Region: Maxilla

edentulous gap	Vmin	Vmax	Lmin	Lmax
6, 11	0.75	2.25	7.50	9.00

7, 10	0.75	1.50	6.40	7.00
8, 9	0.75	2.25	8.50	10.00
6-7, 10-11	1.50	4.50	13.90	16.00
6-8, 9-11	2.25	7.50	22.40	26.00
7-8, 9-10	1.50	3.75	14.90	17.00
6-9, 8-11	3.00	9.00	30.90	36.00
6-10, 7-11	3.75	10.50	37.30	43.00
6-11	4.50	12.75	44.80	52.00

Transitional Region: Mandible

edentulous gap	Vmin	Vmax	Lmin	Lmax
21-24, 25-28	3.00	9.75	25.60	29.00
20-24, 25-29	3.75	12.00	32.30	36.80
19-24, 25-30	4.50	15.00	42.30	48.80
18-24, 25-31	6.00	18.00	51.00	71.20
18-22, 27-31	5.25	14.25	41.00	58.20
18-23, 26-31	5.25	15.75	46.00	64.70
21-22, 27-28	1.50	4.50	13.60	16.00
21-23, 26-28	2.25	6.00	18.60	22.50
20-22, 27-29	2.25	6.75	20.30	23.80
20-23, 26-29	3.00	8.25	25.30	30.30
19-22, 27-30	3.00	9.75	30.30	35.80

Transitional Region: Maxilla

edentulous gap	Vmin	Vmax	Lmin	Lmax
5-8, 9-12	3.00	9.75	29.30	34.00
4-8, 9-13	3.75	12.00	36.00	41.80
3-8, 9-14	4.50	15.00	46.00	53.80
2-8, 9-15	6.00	18.00	55.00	64.20
2-6, 11-15	5.25	14.25	40.10	47.20
2-7, 10-15	5.25	15.75	46.50	54.20
5-6, 11-12	1.50	4.50	14.40	17.00
5-7, 10-12	2.25	6.00	20.80	24.00
4-7, 10-13	3.00	8.25	27.50	31.80
3-7, 10-14	3.75	11.25	37.50	43.80

Table 3

(Tissue Contourers used in Cases of Moderate Atrophy)

Posterior Region: Mandible & Maxilla

edentulous gap	Vmin	Vmax	Lmin	Lmax
5, 12, 21, 28	1.30	3.90	6.9	8.0
4-5, 12-13, 20-21, 28-29	2.60	7.80	13.6	15.8
3, 14, 19, 30	1.30	5.20	10.0	12.0
2-3, 14-15, 18-19, 30-31	2.60	10.40	19.0	22.4

3-5, 12-14, 19-21, 28-30	3.75	6.00	23.6	27.8
2-4, 13-15, 18-20, 29-31	2.60	10.40	25.9	30.4
2-5, 12-15, 18-21, 28-31	7.80	20.80	32.9	38.2

Anterior Region: Mandible

edentulous gap	Vmin	Vmax	Lmin	Lmax
22, 27	1.3	3.9	6.7	8.0
23, 24, 25, 26	1.3	2.6	5.0	6.5
22-23, 26-27	2.6	7.8	13.7	14.5
22-24, 25-27	3.9	13.0	18.7	21.0
24,-25	2.6	5.2	10.0	13.0
22-25, 24-27	5.2	6.0	23.7	27.5
22-26, 23-27	2.5	18.2	28.7	34.0
22-27	7.8	22.1	35.4	42.0

Anterior Region: Maxilla

edentulous gap	Vmin	Vmax	Lmin	Lmax
6, 11	1.3	3.9	7.5	9.0
7, 10	1.3	2.6	6.4	7.0
8, 9	1.3	3.9	8.5	10.0
6-7, 10-11	2.6	7.8	13.9	16.0
6-8, 9-11	3.9	13.0	22.4	26.0
7-8, 9-10	2.6	6.5	14.9	17.0
6-9, 8-11	5.2	15.6	30.9	36.0
6-10, 7-11	6.5	18.2	37.3	43.0
6-11	7.8	22.1	44.8	52.0

Transitional Region: Mandible

edentulous gap	Vmin	Vmax	Lmin	Lmax
21-24, 25-28	5.2	16.9	25.6	29.0
20-24, 25-29	6.5	20.8	32.3	36.8
19-24, 25-30	7.8	26.0	42.3	48.8
18-24, 25-31	10.4	31.2	51.0	71.2
18-22, 27-31	9.1	24.7	41.0	58.2
18-23, 26-31	9.1	27.3	46.0	64.7
21-22, 27-28	2.6	7.8	13.6	16.0
21-23, 26-28	3.9	10.4	18.6	22.5
20-22, 27-29	3.9	11.7	20.3	23.8
20-23, 26-29	5.2	14.3	25.3	30.3
19-22, 27-30	5.2	16.9	30.3	35.8

Transitional Region: Maxilla

edentulous gap	Vmin	Vmax	Lmin	Lmax
5-8, 9-12	5.2	16.9	29.3	34.0
4-8, 9-13	6.5	20.8	36.0	41.8
3-8, 9-14	7.8	26.0	46.0	53.8

2-8, 9-15	10.4	31.2	55.0	64.2
2-6, 11-15	9.1	24.7	40.1	47.2
2-7, 10-15	9.1	27.3	46.5	54.2
5-6, 11-12	2.6	7.8	14.4	17.0
5-7, 10-12	3.9	10.4	20.8	24.0
4-7, 10-13	5.2	14.3	27.5	31.8
3-7, 10-14	6.5	19.5	37.5	43.8

[00248] Tissue contourers may be filled with any of several fluids. These fluids may be compressible or incompressible. Acceptable compressible fluids include air, carbon dioxide, or nitrogen. Acceptable incompressible fluids include sterile water, saline solution or other biocompatible fluids. The tissue contourers may also be filled with a mixture of both a compressible fluid and an incompressible fluid.

[00249] Such a combination of fluids have been determined (1) to support the tissue that is being expanded, preventing it from being crushed or overly compressed, such as during vigorous chewing, and (2) to provide internal tension to strain the tissue even after it expands slightly. If the contourer is partially filled with compressible fluid at a pressure above atmospheric pressure, it will be able to apply a residual contouring force to the tissue being contoured.

[00250] From the foregoing, it will be observed that numerous modifications and variations can be effected without departing from the true spirit and scope of the novel concept of the present invention. For example, any of the various ports described herein may be used with any of the tissue contourer bladders described herein. Any of the tissue contourers show herein may be provided with or without ports. It will be appreciated that the present disclosure is intended as an exemplification of the invention, and is not intended to limit the invention to the specific embodiment illustrated. The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims.